IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ALZA CORPORATION and JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v. // CIVIL ACTION NO. 1:14CV85
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves United States patent 8,163,798 ("the '798 patent") issued to the plaintiffs, Alza Corporation and Janssen Pharmaceuticals, Inc. ("Alza"). The claims in the '798 patent, entitled "Methods and Devices for Providing Prolonged Drug Therapy," are undisputed save one phrase.

The patent-in-suit covers methods and devices for maintaining a desired therapeutic drug effect over a prolonged therapy period, specifically, oral dosage forms that release active pharmaceutical ingredient ("API") within the gastrointestinal tract at an ascending release rate over an extended time period. Some of these dosage forms include an immediate-release dose of API. Alza uses the formulations and methods described in these patents in a commercial product known as CONCERTA®.

I. BACKGROUND

In a letter dated April 1, 2014, the defendant, Mylan Pharmaceuticals, Inc., ("Mylan"), notified Alza that it had filed

an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a tablet containing methylphenidate hydrochloride ("generic tablet").[1] Mylan also filed a certification with the FDA alleging that certain claims of the patent-in-suit are invalid and not infringed by Mylan's manufacture or sale of its generic tablet. Alza responded to Mylan's ANDA by filing this patent infringement action against Mylan pursuant to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"). See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.

In its complaint, Alza contends that the product described in Mylan's ANDA infringes claim 8 in the '798 patent, which is dependent on claim 1. The parties have identified one term from claim 1 in need of construction for which they have proposed competing claim constructions. They also have submitted two (2) agreed claim constructions. Following a claim construction hearing and full briefing of the issues, for the reasons that follow, the Court adopts the following construction.

[1] In the original complaint, Alza had also named Mylan Inc. as a defendant (Dkt. No. 1). The parties agreed to dismiss Mylan Inc. on November 3, 2014 (Dkt. No. 48).

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, the specifications, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). According to a fundamental principle of claim construction, the invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corporation, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the invention. Id.

Claim terms should be construed according to their "ordinary and customary" meaning, which is "the meaning that the term would

have to a person of ordinary skill in the art in question at the time of the invention." Claim construction therefore requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase in question. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. at 1314. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a

technical term.'" Id. at 1315 (quoting Multiform Desiccants,Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, ¶ 1, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v.

Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history of a patent may also provide insight into the meaning of a term or phrase. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Id.

Finally, when determining the ordinary and customary meaning of a term, a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises. Id. Nevertheless, such sources may be reliable if they were publicly available and establish "'what a person of skill in the art would have understood disputed claim language to mean.'" Id. at 1314 (quoting Innova, 381 F.3d at 1116).

It is with these legal principles in mind that the Court turns to the construction of the disputed term in the patent-in-suit.

III. ANALYSIS

CONCERTA®, which is used to treat attention deficit hyperactivity disorder ("ADHD") and attention deficit disorder ("ADD") in children and adults, is a tablet consisting of an immediate-release component and a sustained-release component. The

immediate-release component "refers to a dose that is substantially completely released within a time period of about 1 hour or less and, preferably, about 30 minutes or less." '798 Patent, col. 9:27-28. The sustained-release component releases drug for an extended time period wherein more of the API is released during the second time interval than during the first time interval, and more of the API is released during the third time interval than during the second time interval. '798 Patent, col. 22:46-61.

According to Alza, CONCERTA® is an improvement over the prior art because older treatments for ADHD/ADD, including Ritalin® and Ritalin SR®, either require multiple administrations throughout the day, or, in the case of extended-release tablets, diminish in effectiveness throughout the day (Dkt. No. 72 at 8-9). Studies demonstrated that CONCERTA®, with its ascending release rate, "was more effective than the flat plasma drug concentration profile in controlling the symptoms of ADHD throughout the course of the day, and was at least twice as effective as the twice-a-day dosing regimen." '798 Patent, col. 21:29-60. The parties' dispute stems from claim 1 of the '798 patent, which claims an immediate-release/sustained-release tablet.

Alza construes the disputed term, "said dosage form releases said methylphenidate over a period comprising first, second, and

third sequential one-hour time intervals," as used in claim 1 of the '798 patent, to mean "said dosage form releases said methylphenidate over a period comprising first, second, and third sequential one-hour time intervals **starting at the beginning of dissolution testing**." Mylan construes it to mean "said dosage form releases said methylphenidate over **any** three-hour period, in which the three-hour period is divided into first, second, and third sequential one-hour time intervals."

A. The Claims

Claim 1 of the '798 patent reads as follows:

> 1. An oral tablet dosage form for the treatment of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder in a subject comprising:
>
> an immediate release portion comprising methylphenidate or a pharmaceutically effective salt thereof; and
>
> a sustained release portion comprising methylphenidate or a pharmaceutically effective salt thereof and a pharmaceutically acceptable carrier,
>
> wherein:
>
> **said dosage form releases said methylphenidate over a period comprising first, second, and third sequential one-hour time intervals,** and
>
> said sustained release portion releases more of said methylphenidate during said second interval than during said first interval, and more of said methylphenidate during said third interval than during said second interval.

'798 Patent, 22:45-61 (emphasis added).

Alza argues that, under the plain language of claim 1, the

"first, second, and third sequential one-hour time intervals" clearly begin at the start of dissolution testing, or t=0 (Dkt. No. 72 at 16). Claim 1 describes the tablet as being comprised of both an immediate-release and a sustained-release portion. '798 Patent, col. 22:45-61. At t=0, or the time of administration, the immediate-release component of the tablet activates and begins to release drug, which is completely released "within a time period of about 1 hour or less and, preferably, about 30 minutes or less." '798 Patent, col. 9:27-29. Alza contends that, because the immediate-release component necessarily releases during the first time interval, or t=1, the rest of "said dosage form," the sustained-release component, also begins releasing during the "first, second, and third sequential one-hour time intervals." Id.

In other words, the reference in claim 1 to "said dosage form," defined as a dosage form comprised of immediate-release and sustained-release components, necessarily means that the time intervals are defined by reference to when the "dosage form" as a whole begins releasing API. The dosage form as a whole begins releasing API at the beginning of dissolution testing, or t=0; therefore, the "first, second, and third sequential one-hour time

intervals" refer to t=1, t=2, and t=3.[2]

Mylan contests that dissolution testing begins immediately when the dosage form is placed in the dissolution apparatus (Dkt. No. 82 at 5-6). It also argues that the plain language of claim 1 only provides that the product releases API during "any" three sequential one-hour time periods, and not necessarily t=1, t=2, and t=3 (Dkt. No. 78 at 15-16). Mylan contends that many of the examples in the specification establish an ascending release rate for more than three hours, thus supporting its construction that the sustained-release component could begin releasing API either at t=0 or at a later point in dissolution testing.

In the Court's view, the plain language of claim 1 supports Alza's proposed construction. The inventors' use of the term "said," with the common meaning "aforesaid" or "abovementioned," clearly indicates their intent to refer back to the dosage form containing both immediate-release and sustained-release components.

[2] Mylan's argument that claim 2 of the '798 patent dictates a contrary result is unpersuasive. Claim 2 provides for a dosage form of claim 1 where the API released "during said first interval only includes methylphenidate released from said immediate release portion." '798 Patent, col. 22:62-65. Because the Court presumes that the independent claim 1 does not contain the limitations of dependent claim 2, Phillips, 415 F.3d at 1313-14, it follows that, in claim 1, the sustained-release portion begins to release drug during "said first interval," the same time when the immediate-release portion is activated. The Court reaches this same result by simply looking at the plain language of claim 1.

Black's Law Dictionary, 665 (4th pocket ed. 2011). See Creative Internet Advertising Corp. V. YahooA, Inc., 476 Fed. Appx. 724, 728-29 (Fed. Cir. 2011) (construing "said" to refer back to the antecedent phrase); Intamin Ltd. v. Magnetar Techs. Corp., 483 F.3d 1328, 1333 (Fed. Cir. 2007) ("The use of the word 'said' in a claim refers to an earlier use of the term in the claim."). "[S]aid" dosage form, which comprises both immediate-release and sustained-release components, begins releasing API immediately upon commencement of dissolution testing, or at t=0. '798 Patent, col. 9:27-37. This is so because the immediate-release component, usually an overcoat, begins to dissolve immediately when dissolution testing begins. It follows logically that the other half of "said dosage form," the sustained-release component, also begins releasing drug at t=0 at a rate that substantially ascends over the "first, second, and third sequential one-hour time intervals," or t=1, t=2, and t=3.

Mylan's proposed construction ignores the plain language of the patent, particularly the antecedent term "said." "A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (internal citations omitted).

Furthermore, Mylan's proposed construction makes little sense given the inventors' clear intention to provide "continuous effective drug therapy over a prolonged therapy period." '798 Patent, col. 10:45-46. Under Mylan's proposed construction, the immediate-release portion would begin releasing API immediately, at t=0, but the sustained-release portion could begin to release API at any time, including hours after the drug had been released from the immediate-release component. This result would create the same "peaks and troughs" that plagued earlier inventions, and that the inventors of CONCERTA® specifically avoided. '798 Patent, col. 21:42-48.

B. The Specification

A closer examination of the patent specification further supports Alza's proposed construction. Alza contends that every reference to the "first, second, and third sequential one-hour time intervals" in the specification of the '798 patent refers to the first, second, and third one-hour intervals after the start of dissolution testing (Dkt. No. 72 at 11-14, 18-20). Mylan argues that Alza is improperly importing limitations from preferred embodiments in the specification into the claim, and that, at any rate, the specification never states that dissolution measurement must begin at t=0 (Dkt. No. 82 at 5-6).

Mylan's argument that Alza is asking the Court to commit the "cardinal sin" of claim construction is well-taken. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324, 1326-28 (Fed. Cir. 2002). It is well-established that the Court cannot read limitations from the specification into the claims. Id. at 1326. On the other hand, the claims must be interpreted in light of the specification, which provides "context" for claim construction. Id. at 1326-27. The United States Court of Appeals for the Federal Circuit has explained that "an accused infringer cannot overcome the 'heavy presumption' that a claim term takes on its ordinary meaning simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." Id. at 1327 (citing CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)). This is not the situation at bar, however; rather, the context provided by the specification supports the plain language of claim 1.

The specification establishes that the inventors' goal was to control patients' behavioral symptoms of ADD and ADHD during the daytime, but discontinue therapy during the afternoon and evening hours due to the side effects typically associated with methylphenidate, a stimulant. '798 Patent, col. 6:62-67, col. 7:1-2. They sought to accomplish this goal by designing a product

with a substantially ascending release rate. '798 Patent, col . 7:41-46. An ascending release rate solved the problems of (1) peaks and troughs associated with multiple administrations of immediate-release products, and (2) the delay in onset and lack of efficacy associated with previous sustained-release products. '798 Patent, col. 7:5-40.

Given this background, the inventors designed a product with an immediate-release "overcoat" that would immediately supply an initial dose of the drug, and a sustained-release component that would gradually become hydrated and begin releasing drug.[3] '798 Patent, col. 8:32-40. The specification provides that the time of drug administration is zero hours, or t=0, with each hour following administration designated as t=1, t=2, and so on. '798 Patent, col. 8:45-48. It also instructs that "in vitro drug release rates" are to be obtained "at the specified time following implementation of an appropriate dissolution test." '798 Patent, col. 9:9-14.

Importantly, for a clinically effective ascending release rate to be achieved, the product must release API at an ascending rate "beginning at t=0 hours and continuing through at least the mid-point, and preferably beyond the midpoint, of the relevant T_{90} of

[3] The sustained-release system differs from a delayed-release delivery system like the one described by Mylan. '798 Patent, col. 2:50-52.

the dosage form."[4] '798 Patent, col. 10:9-20. For example, if a dosage form releases 90% of its drug at t=8, or eight hours after administration, the ascending release rate of the drug should continue through at least t=4.[5] See '798 Patent, col. 10:11-31. Although Mylan vigorously challenges the applicability of this provision of the specification (Dkt. No. 82 at 6), it is useful to provide the context within which claim 1 must be considered. Teleflex, 299 F.3d at 1326-27.

Given this background, and without even considering any preferred embodiments, the Court concludes that the specification squarely supports Alza's proposed construction.[6] The goal of the invention, to provide an effective, long-lasting plasma concentration, would be undermined by Mylan's proposed construction, which could result in the same peaks and troughs specifically avoided by the inventors. Furthermore, the clinical

[4] T_{90} refers to the commonly-used reference measurement for evaluating drug release from oral dosage forms. T_{90} for a dosage form means the time at which 90% of drug within a dosage form has been released. '798 Patent, col. 9:23-26.

[5] As Alza mentioned during oral argument, claim 1 encompasses an ascending release rate of at least three hours, but a product with a longer ascending release rate would also infringe the claim.

[6] Notably, however, every example in the specification provides for an ascending release rate beginning at t=0. See, e.g., '798 Patent col. 14:25-35, col. 15:25-42, col. 16:45-68, col. 17:55-65, col. 20:36-50.

effectiveness of the product depends upon an ascending release rate that extends throughout the midpoint of the T_{90} of the dosage form. It therefore makes no sense that claim 1 should cover a product with an ascending release rate beginning at t=4 or t=5. Finally, the specification mentioned delayed release forms similar to those mentioned by Mylan, but specifically declined to describe the invention in those terms. '798 Patent, col. 2:50-52. In short, the specification comports with the plain language of claim 1.

C. The Prosecution History

The prosecution history of the patent-in-suit further undermines Mylan's proposed construction. Mylan argues that the inventors stated that their claims were not limited to "the" second time interval, but, rather, a "second or succeeding time interval," thus indicating their intent to broadly claim an ascending release rate either at the beginning of or later during dissolution testing (Dkt. No. 78 at 17). It also contends that the inventors abandoned claims specifically referencing the release rate beginning at t=0. Id. at 17-18. According to Mylan, the prosecution history makes clear that the inventors did not intend to limit the measurement of "first, second, and third sequential one-hour time intervals" from the beginning of dissolution testing. Id. at 18.

Alza contends that the amendments made during prosecution are

inapplicable to claim 1 because none of the cancelled claims required a dosage form including an immediate-release component (Dkt. No. 79 at 9). The amendments, therefore, shed little light on the scope of claim 1. Id. Alza submits that, after claim 1 was added to the list of pending claims, it was not further amended except to add the word "tablet." Id. at 10.

It is well-established that the prosecution history may provide insight into the meaning of a term or phrase, and that the inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Phillips, 415 F.3d at 1317. "[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. If a claim has a plain and ordinary meaning, the Federal Circuit has found that "the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal."[7] GE Lighting Solutions, LLC v. AgiLight, Inc., 750

[7] Lexicography, which is not at issue here, refers to when a patentee (1) clearly defines the disputed claim term, and (2) clearly expresses an intent to define the term. GE Lighting, 750 F.3d at 1309.

F.3d 1304, 1308-09 (Fed. Cir. 2014) (citing Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). As relevant here, the "exacting" standard for disavowal requires that "the specification [or prosecution history] make[] clear that the invention does not include a particular feature." Id. (quoting SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001)).

During prosecution, the inventors amended claims 35, 36, and 37 to include language measuring the release rate "from a first periodic interval that begins at time t=0" to "about 5.5 to 8 hours following said administration." March 25, 2008, Reply Pursuant to 37 C.F.R. § 1.116, at 2. Mylan argues that those claims, which were eventually cancelled, establish that the inventors knew how to limit a claim, but affirmatively chose to not do so in the remaining claims (Dkt. No. 78 at 17-18). See March 20, 2009, Reply Pursuant to 37 C.F.R. § 1.116, at 2 (cancelling claims 36-39 and 41-44); March 25, 2008, Reply Pursuant to 37 C.F.R. § 1.116, at 2 (cancelling claim 35).

In October, 2009, the inventors added new claim 45, which eventually issued with substantially the same language as claim 1. October 15, 2009, Reply Pursuant to 37 C.F.R. § 1.116, at 2. At that time, claim 40, as amended, was still pending. Claim 40

provided for "[a] dosage form comprising a pharmaceutically acceptable composition comprising methylphenidate or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier, wherein said dosage form provides an ascending release rate of said methylphenidate beginning with a first periodic interval that begins at time t=0 and continuing through about 5.5 hours following said administration." Id. (emphasis added). The inventors noted that new claim 45 is "directed to dosage forms that achieve an ascending rate of release of methylphenidate from a first time interval to a second time interval, and an ascending rate of release of methylphenidate from the second time interval to third time interval." Id. at 6.

The patent examiner withdrew claims 45-51 as not reading on the invention originally examined, and rejected claim 40. Non-Final Office Action, November 12, 2009, at 3. The inventors responded by arguing that, although claim 40 does not explicitly include an immediate-release component, "the scope of that claim is such that it includes this feature." January 7, 2010, Reply Pursuant to 37 C.F.R. § 1.116, at 2.

The patent examiner eventually required restriction among claim 40 and claims 45-51 pursuant to 35 U.S.C. § 121. See April 22, 2010, Reply Pursuant to 37 C.F.R. § 1.116, at 2. The inventors

then elected to pursue pending claims 45-51, which ultimately issued as claims 1-7 of the '798 patent. April 22, 2010, Reply Pursuant to 37 C.F.R. § 1.116, at 2.

Although cancelled claim 40, which provided for an ascending release of drug beginning at t=0, did not specifically include an immediate-release component, the inventors argued for such an application. See January 7, 2010, Reply Pursuant to 37 C.F.R. § 1.116, at 2 (arguing that, although claim 40 does not explicitly include an immediate-release component, "the scope of that claim is such that it includes this feature"). Importantly, that they did so supports Mylan's argument that the inventors had a claim that 1) specifically provided for an ascending release rate beginning at t=0, and 2) at least arguably included an immediate-release component.

It is clear, however, that the inventors affirmatively chose to proceed with claims 45-51, and not claim 40. April 22, 2010, Reply Pursuant to 37 C.F.R. § 1.116, at 2. Claim 45 explicitly included both immediate-release and sustained-release components, thus clarifying the uncertainty in claim 40. It also included plain language indicating that "said dosage form" releases the API over three sequential one-hour intervals. As explained above, these three time intervals begin at the start of dissolution

testing, or t=0. See GE Lighting Solutions, 750 F.3d at 1308-09 (stating that the prosecution history must make it clear that the invention does not include a particular feature in order to disavow the plain language of the claim). In claim 45, the inventors took out the specific reference to t=0, but added language indicating when the ascending release should begin. The Court therefore rejects Mylan's invitation to rely on the prosecution history to contravene the plain language of claim 1.

IV. CONCLUSION

For the reasons discussed, the Court **CONSTRUES** the contested claim term as follows:

1. "[S]aid dosage form releases said methyphenidate over a period comprising first, second, and third sequential one-hour time intervals" means "said dosage form releases said methylphenidate over a period comprising first, second, and third sequential one-hour time intervals starting at the beginning of dissolution testing."

Further, the Court adopts the parties' agreed claim constructions and **CONSTRUES** the following terms and phrases as follows:

1. "Releases" means "releases according to an in-vitro dissolution test;" and,

2. "Said dosage form is osmotic" means "said oral tablet utilizes osmotic pressure to generate a driving force for imbibing fluid into a compartment formed, at least in part, by a semipermeable wall that permits free diffusion of fluid but not drug or osmotic agents."

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: July 6, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE